

Remarks:

In this Amendment, Applicant has cancelled claims 1, 6-7, 11-15, 19-21, 27 and 29 and amended claims 2-5, 8, 10, 16-18, 22-26 and 30. The drawings have also been amended to meet U.S.C code requirements. Original claims 9 and 28 remain unchanged. The amendments have been made to specify various embodiments of the present invention and overcome the rejection. The amendments are largely editorial in nature and it is respectfully submitted that no new matter has been introduced by the amended claims and drawings. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

OBJECTION TO THE DRAWINGS:

The drawings have been objected to under 37 CFR 1.83(a) as not showing the features of claims 14 and 15.

Claims 14 and 15 have been cancelled with this response rendering this objection moot.

OBJECTION TO CLAIM 20:

Claim 20 is objected to as the examiner finds that claim 20 cannot depend from claim 1, but must instead depend from claim 19, as claim 20 recites 'the container' which is a limitation set forth only in claim 19.

Claim 20 has been cancelled rendering this objection moot.

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 1-6, 10-17, 22-26, 28 and 29 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Liedtke (US 5,686,112) hereinafter Liedtke.

Applicant traverses the rejection and respectfully submits that the present-claimed invention is not anticipated by the cited reference. Firstly, Claims 1, 6, 11-15 and 29 have been cancelled rendering the rejection moot in respect of these claims. Remaining claims 2-5, 10, 16-17, 22-26, and 28 have been amended to be either directly or indirectly dependent on currently amended claim 30, previously found to be novel, which includes the feature that '*...a portion of at least one well is transparent and the solution colors seen through the well or wells are used as indicia.*' The basis for this amendment may be found throughout the specification and incorporates the previously claimed feature of claim 7. It is respectfully submitted that such features are not disclosed or suggested in Liedtke. Liedtke only discloses topical formulations used in a blister pack where the molded body includes printed indicia. No disclosure is made regarding use of a transparent well and colored topical formulations.

In addition, the advantage of using formulation color and transparent wells is not provided by the pack and methods described in Liedtke. For example, the packages described in Liedtke need to be printed in advance specifically for the desired end use such as with days of the week. In the present invention, only one type of blister pack need be manufactured and there is complete flexibility as to what colored formulation or formulations the manufactured pack is used for as it is the formulation color that determines the end use.

The examiner notes in their report that Liedtke refers to indicia, which can be numeric or color. It is respectfully submitted that the indicia referred to is printed on the pack and not a color inherent to the formulation itself.

The examiner refers to two Federal Court decisions *In re Gulack* and *In re Ngai*. These cases are mentioned regarding the question of whether or not a functional relationship exists between printed matter and a container. It is respectfully submitted that printed matter per se is not the subject of the present invention as claimed in Claim 30 as currently amended. Instead, it is the color of the formulation within transparent wells that is the key indicia. It is further submitted that the color relationship allows the user to determine characteristics of the formulation, for example, when to take the formulation or what the formulation contains. Given this relationship it is submitted that there is a strong functional relationship between the indicia (formulation color) and the blister pack thus overcoming the rejections found in Gulack and Ngai.

As claims 2-5, 10, 16-17, 22-26, and 28 are now dependent either directly or indirectly on currently amended claim 30 which includes the novel feature of transparent wells and colored formulations as indicia, it is respectfully submitted that claims 2-5, 10, 16-17, 22-26, and 28 as currently amended are now also novel.

Therefore, the rejection under 35 U.S.C. § 102 (b) has been overcome. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103:

Claim 27 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liedtke and the Examiner Official Notice.

Claim 27 has been cancelled rendering this rejection moot.

Claims 7-9 and 30 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liedtke in view of Hughes (US 6,139,873) hereinafter Hughes, and in view of McDaniel (US 2002/0120225) hereinafter McDaniel.

Claim 7 has been cancelled rendering this rejection moot in respect of this claim. Claim 30 has been amended and claim 8 amended to be dependent on amended claim 30. Claim 9 remains dependent on claim 8.

Applicant traverses the rejection with respect to claims 8-9 and 30 and respectfully submits that the embodiments of the presently claimed invention are not obvious over the cited prior art references. As indicated above, there are significant differences between the embodiments of the present invention as amended and the disclosures in Liedtke, Hughes and McDaniel.

Liedtke describes topical formulations presented to the user in the form of a blister pack. Liedtke describes that indicia including numerals and colors may be used as indicia on the pack. It is respectfully submitted that color as an indicia is not disclosed or suggested in respect of the solution itself, nor is the use of transparent wells to view colored solution. In fact, examples provided in Liedtke are all directed towards the use of printed numerical indicia on the pack itself.

Hughes describes hormone treatments using a combination of three different hormones to achieve a desired effect. Formulations described are almost exclusively limited to tablets for oral administration and ointments are only mentioned in passing with no examples provided as to their use. It is accepted by the applicant that in col14, lines 34-49 color coding is described in passing. Like Liedtke though, color is referred to as being for use as an indicia on the pack. It is respectfully submitted that no disclosure

nor suggestion is made regarding use of the solution itself acting as the indicia and being viewable through transparent wells in a blister pack.

McDaniel is directed to methods of optimizing ultrasound parameters to enhance transport of topical agents into various skin tissues. It is acknowledged that page 6 and Figure 9 of McDaniel describes use of color as indicia but, like Liedtke and Hughes, color is printed on the 'treatment card' (pack). In all of the examples provided in McDaniel, different colors are used also in conjunction with written indicia as well. It is respectfully submitted that no disclosure or suggestion is made of a topical solution color being the indicia and the pack including transparent wells through which the solution is viewed.

Given that Liedtke, Hughes and McDaniel do not describe or suggest even when combined, the claimed feature of claim 30 as currently amended, it is submitted that claim 30 as currently amended cannot be considered obvious over these documents. It is further submitted that none of the products of Liedtke, Hughes and McDaniel address the problem solved by the claims of the present invention. As discussed above an advantage of using formulation color and transparent wells is that the packs used in the present invention do not need to be printed in advance specifically for the desired end use such as with written indicia such as days of the week. In the present invention, only one type of blister pack need be manufactured and there is complete flexibility as to what colored formulation or formulations the manufactured pack is used for as it is the formulation color that determines the end use. By contrast, the packs of Liedtke, Hughes and McDaniel all require specifically tailored packs for each application that the pack is used for. Such methods become particularly unwieldy where, for example, differing solutions or concentration of solutions are used for different patients.

Further, if the application described in the claims of the present invention were obvious, why then are there no products on the market using this method of indicia.

Applicant has found considerable interest in the invention product and as such it is respectfully submitted that clearly inventive value is attributable to the claimed apparatus.

Finally, Applicant contends that it would not be obvious for a person skilled in the art to combine the references of Liedtke, Hughes and McDaniel. Each reference has a very different focus. Liedtke is directed primarily towards a blister pack for packaging and storage of topical formulations. Hughes is directed primarily towards oral tablet formulations containing a mix of three specific hormones. McDaniel is directed to methods of optimizing ultrasound parameters to enhance transport of topical agents into various skin tissues. McDaniel in particular appears to have little relevance to the claims of the present invention and therefore it is submitted, should be removed from consideration.

Therefore, the rejection under 35 U.S.C. § 103(a) in regard to claim 30 has been overcome and, as claims 8 and 9 are dependent directly in the case of claim 8 and indirectly in the case of claim 9, the rejection of these claims should also be overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 103(a) towards claims 8-9 and 30 is respectfully requested.

Claim 18 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liedtke and Schaefer (DE 198 31 263 A1) hereinafter Schaefer.

Applicant traverses the rejection with respect to claim 18 as currently amended and respectfully submits that the embodiment of the presently claimed invention is not obvious over the cited prior art reference. As indicated above, there are significant and non-obvious differences between the embodiment of the present invention as claimed in claim 30 as amended compared to the disclosures in Liedtke, Hughes and McDaniel. It is respectfully submitted that these embodiments as claimed in amended claim 30 are not disclosed in Schaefer. As claim 18 as currently amended is now dependent on claim

30 as amended, claim 18 must now also be considered inventive and non-obvious over Liedtke, Hughes and McDaniel.

Claims 19-21 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Liedtke and Haber (US 5,405,011) hereinafter Haber, and Hermelin et al (US 6,375,956) hereinafter Hermelin.

Claims 19-21 have been cancelled rendering this rejection moot.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

Waikiwi Corporation

By: 

Mark V. Moorfoot CFO

Date: 9. 6. 05